CONCLUSION OF LAW

"The prayer of the amended information in libel should be granted. The labels on the preparation known as 'Sulfa-Seb' and 'Sulfa-Ped' seized by the marshal should be condemned. The false and misleading labels on such preparations should be destroyed."

On the same date, judgment was entered condemning and ordering the destruction of the labels of the products. It was further ordered that when the labels had been destroyed the products should be returned to the claimant for use in compliance with the law.

1361. Misbranding of citrate of magnesia. U. S. v. 200 Cases of Citrate of Magnesia. Default decree of condemnation and destruction. (F. D. C. No. 11648. Sample No. 23693–F.)

On or about January 20, 1944, the United States attorney for the District of New Jersey filed a libel against 200 cases, each containing 24 bottles, of citrate of magnesia at Atlantic City, N. J., alleging that the article had been shipped on or about November 5, 1943, from Brooklyn, N. Y., by the National Magnesia Co.; and charging that it was misbranded. The labeling consisted of the words "Citrate of Magnesia" blown into the glass of the bottles, and the words "Citrate of Magnesia U. S. P." on the bottle cap.

The article was alleged to be misbranded (1) in that it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor and an accurate statement of the quantity of the contents; (2) in that its labeling failed to bear adequate directions for use; and (3) in that its labeling failed to warn that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use of the preparation might result in dependence on laxatives.

On October 27, 1944, no claimant having appeared, judgment of condemnation was entered and it was ordered that the contents of the bottles be destroyed and that the empty bottles be released to the consignee from whom the product was seized.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

1362. Adulteration of sterile distilled water and dextrose solution. U. S. v. Winthrop Chemical Co., Inc. Plea of guilty. Fine, $18,000. (F. D. C. No. 11420. Sample Nos. 6962–F, 6963–F, 20251–F, 20568–F, 20569–F, 23819–F, 39113–F, 45035–F, 51318–F, 52893–F, 53059–F.)

On May 25, 1944, the United States attorney for the Southern District of New York filed an information against the Winthrop Chemical Co., Inc., New York, N. Y., alleging shipment of quantities of the above-named products between the approximate dates of May 3 and August 6, 1943, from the State of New York into the States of Missouri, Connecticut, Rhode Island, Massachusetts, Virginia, Pennsylvania, and Illinois.

Examination disclosed that all shipments of the sterile distilled water contained pyrogens; that certain shipments of the article contained undissolved material; and that one shipment was contaminated with living micro-organisms. The United States Pharmacopoeia requires that water for injection, which the article purported to be, shall be sterile, free from pyrogens, and free from any turbidity or undissolved material.

Examination of the dextrose solution disclosed that it contained pyrogens and undissolved material, and that a portion also was contaminated with viable mold. The United States Pharmacopoeia requires that dextrose injection or dextrose ampuls, which the article purported to be, shall be sterile and free from pyrogens and undissolved material.

The articles were alleged to be adulterated in that the sterile distilled water purported to be water for injection and the dextrose solution purported to be dextrose injection or dextrose ampuls, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, but the quality and purity of the articles fell below the standard set forth in that compendium; and the differences in quality and purity of the articles from the official standards were not plainly stated, or stated at all, on their labels. The articles were alleged to be adulterated further in that pyrogens and undissolved material had been mixed or packed with all lots of the articles, and mold had been mixed or packed with a portion of the dextrose solution, so as to reduce the quality of the articles.

On October 4, 1944, a plea of guilty having been entered on behalf of the corporation, the court imposed a fine of $1,500 on each of the 12 counts in the information, a total fine of $18,000.

1363. Adulteration and misbranding of Gestrone Chorionic Gonadotropin, and adulteration of chorionic gonadotropic hormone. U. S. v. Pro-Medico Laboratories, Inc., and Samuel Heller. Pleas of guilty. Corporate defendant fined $750, and individual defendant sentenced to serve 3 months in jail. (F. D. C. No. 7745. Sample Nos. 54960–E, 54961–E, 77049–E.)

On June 29, 1943, the United States attorney for the Eastern District of New York filed an information against the Pro-Medico Laboratories, Inc., Brooklyn, N. Y., and Samuel Heller, president of the corporation, alleging shipment of quantities of the above-named products on or about April 28 and May 27, 1942, from the State of New York into the State of Pennsylvania.

The chorionic gonadotropic hormone and a portion of the Gestrone Chorionic Gonadotropin were alleged to be adulterated in that their strength differed from and their quality fell below that which they purported and were represented to possess, since the former was represented to possess in each cubic centimeter a physiological activity of 500 International Units of anterior pituitary-like sex hormone, and the latter was represented to contain in each cubic centimeter 100 International Units of anterior pituitary-like hormone, whereas the former possessed not more than 83.5 International Units and the latter not more than 17.2 International Units of anterior pituitary-like sex hormone in each cubic centimeter.

The remainder of the Gestrone Chorionic Gonadotropin was alleged to be misbranded in that certain statements in its labeling were false and misleading since they represented and suggested that the article possessed in each cubic centimenter a physiological activity of 500 International Units of anterior pituitary-like sex hormone and that it had been physiologically standardized to that potency, whereas it possessed a physiological activity of not more than 83 International Units of anterior pituitary-like sex hormone in each cubic centimeter.

On January 10, 1945, pleas of guilty having been entered on behalf of the defendants, the court fined the corporate defendant $250 on each of 3 counts, a total fine of $750. The individual defendant was sentenced to 3 months in jail on each of the 3 counts, the sentences to run concurrently.

1364. Adulteration of calcium chloride. U. S. v. Pro-Medico Laboratories, Inc., and Samuel Heller. Pleas of guilty. Fines, $250 against the corporate defendant and $500 against the individual defendant. (F. D. C. No. 11425. Sample Nos. 36460–F, 36476–F.)

On September 12, 1944, the United States attorney for the Eastern District of New York filed an information against the Pro-Medico Laboratories, Inc., Brooklyn, N. Y., and Samuel Heller, president of the corporation, alleging shipment of a quantity of calcium chloride on or about September 25, 1943, from the State of New York into the State of Colorado.

The article was alleged to be adulterated in that it purported to be and was represented as ampuls of calcium chloride, an aqueous ampul solution the name of which is recognized in the National Formulary, an official compendium, but its quality or purity fell below the official standard since the National Formulary provides that aqueous ampul solutions shall be substantially free from undissolved material, whereas the article was not substantially free from undissolved material; and its difference in quality or purity from the official standard was not plainly stated, or stated at all, on its label.

On January 10, 1945, pleas of guilty having been entered on behalf of the defendants, the court imposed a fine of $250 against the corporate defendant and a fine of $500 against the individual defendant.

1365. Adulteration and misbranding of potassium chloride. U. S. v. Frederick A. Klenk (Excel Pharmacal Co.). Plea of guilty. Fine, $250. (F. D. C. No. 9678. Sample No. 9169–F.)

On August 3, 1944, the United States attorney for the Southern District of New York filed an information against Frederick A. Klenk, trading as the Excel Pharmacal Co., New York, N. Y. It was alleged in the information that on or about June 1, 1942, the defendant sold and delivered to the Columbia Medical Laboratories, New York, N. Y., a quantity of an article labeled as "Potassium Chloride"; that at or about the time of the sale and delivery, the defendant furnished to the Columbia Medical Laboratories an invoice containing a guaranty that the article was not adulterated or misbranded within the meaning of the "Federal Food and Drug Act"; that on or about September 22, 1942, the holder of the guaranty introduced and delivered for introduction into interstate com-